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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,091	09/30/2003	Jean Beaupre	END5101.0515146	4756

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EXAMINER

POUS, NATALIE R

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/675,091

Applicant(s)

BEAUPRE, JEAN

Examiner

Natalie Pous

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/5/06.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the connecting member couplings, and the band at a midpoint of the device must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to under 37 CFR 1.83(a) because they fail to show couplings (20), and crowns (114, 116) as described in the specification. Any structural

detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites the limitations "the applier, the actuating member and the distal ring" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 2 and 10 rejected under 35 U.S.C. 102(e) as being anticipated by Park et al. (US 2003/0120292).

Regarding Claim 1, Park teaches an anastomosis device, comprising: a first plurality of arcuate members (first end of device 10) arranged in a first position in a cylindrical crown shape with each arcuate member having legs overlapping at least one adjacent arcuate member; and a second plurality of arcuate members arranged in a first position in an inverted cylindrical crown shape with each arcuate member having legs overlapping at least one adjacent arcuate member of the second plurality (second end of device 10) and connected (it is noted that Park is silent as to the method of making the device however, the term connected is broad and may encompass portions integrally formed) to a leg of an arcuate member of the first plurality (fig. 2); wherein the woven tube thus formed is operably configured to transform into a second position comprising a hollow rivet shape (fig. 1) with each arcuate member outwardly deflected from a longitudinal axis of its respective cylindrical crown toward apposing arcuate members of the other cylindrical crown.

Regarding Claim 2, Park teaches the anastomosis device of claim 1, wherein the arcuate members comprise a shape memory effect alloy (Paragraph 32).

Regarding Claim 10, Park teaches an anastomosis ring device, comprising a plurality of arcuate members (20') operably configured to be arranged into two crowns attached to one another to present petal circumferentially hinged at a circular midpoint (from fig. 2 to fig. 3a), each arcuate member comprising a pair of diverging connected legs (18).

Claims 9 is rejected under 35 U.S.C. 102(e) as being anticipated by Suyker et al. (US 6485496).

Suyker teaches an anastomosis ring device, comprising: a means for forming a half cylinder (2) which actuates into a first apposing member about a midpoint at an anastomosis tissue juncture; and a means for forming an inverted half cylinder (3) which actuates into a second apposing member at the midpoint at the anastomosis tissue juncture (fig. 3).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3-7 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park in view of Vesely (US 6569196) and further as a matter of design choice.

Park teaches all limitations of preceding dependent claim 10, and further teaches a petal formed by the first arcuate member actuating generally in a plane with the respective attached arcuate members pivoting about a cylindrical midpoint of the anastomosis device and wherein

Park fails to teach the method of forming the device further comprising a pin and recess hinge along the midline of the device. Vesely teaches a medical implant wherein the members of the annular device are coupled by rigid pin hinges in order to ensure flexibility between the connected adjacent segments. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Park with pin and recess hinges along the midline in order to ensure flexibility between the connected adjacent segments.

The combination of Park and Vesely teaches a pin and recess hinge as described above, but fails to teach connecting members comprising a selected one of a group consisting of a snap fit, a glue, an ultrasonically welded portion, and a thermally melted polymer. It would have been an obvious matter of design choice to provide the combination of Park and Vesely with one of these connection members since such connections are well known in the art and it would be obvious to substitute the connection of combination of Park and Vesely with another connection since it appears that the combination of Park and Vesely performs the task of ensuring flexibility between the connected adjacent segments equally well as that of the disclosed application.

Claims 1, 3 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evard (US 6616675) in view of Park.

Evard teaches an anastomosis device, comprising the following:

- a first plurality of arcuate members (20) arranged in a first position in a cylindrical crown shape;
- a second plurality of arcuate members (20) arranged in a first position in an inverted cylindrical crown shape and connected (via portion 36) a leg of an arcuate member of the first plurality (fig. 4'); wherein the woven tube thus formed is operably configured to transform into a second position comprising a hollow rivet shape (fig. 4'') with each arcuate member outwardly deflected from a longitudinal axis of its respective cylindrical crown toward apposing arcuate members of the other cylindrical crown (fig. 4'').
- Wherein the legs are attached to each other by a connecting member (36)
- Wherein the connecting member comprises a band (36) at the midpoint of the device and connected to each arcuate member.

Evard fails to teach with each arcuate member having legs overlapping at least one adjacent arcuate member. Park teaches an anastomosis device wherein the legs of the arcuate members overlap in order to provide more coverage on the vessel wall. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Evard with overlapping legs as taught by Park in order to provide more coverage on the vessel wall.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP
8/17/06


ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
